

Original Research Article

Clinical effectiveness of co-amoxiclav in upper respiratory tract infections: results from a large multicenter real-world evidence study

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ABSTRACT

Background: Upper respiratory tract infections (URTIs) are among the most common reasons for outpatient consultations and antibiotic prescribing. Although many URTIs are viral, bacterial infections and secondary bacterial complications often require antimicrobial treatment. Co-amoxiclav is widely used for bacterial respiratory infections; however, large-scale real-world evidence (RWE) remains limited. This study evaluated the effectiveness and prescribing patterns of co-amoxiclav in routine clinical practice.

Methods: This multicenter, retrospective, medical record-based RWE study included patients with URTIs who received co-amoxiclav across participating centers. Demographic characteristics, prescribing patterns, and treatment outcomes were evaluated in pediatric (≤ 12 years) and adult (> 12 years) populations. Clinical outcomes were categorized as cure, improvement, or no improvement.

Results: A total of 12,986 patients were included, comprising 1,116 pediatric and 11,870 adult patients. Unspecified URTI was the predominant diagnosis (81.6%), followed by tonsillitis, acute otitis media (AOM), pharyngitis, sinusitis, and laryngitis. Suspension formulations were prescribed more frequently in pediatric patients, whereas tablet formulations predominated among adults. Twice-daily dosing was the most commonly prescribed regimen across age groups. Overall clinical success (cure plus improvement) was achieved in 12,970 patients (99.88%). Complete clinical cure was documented in 12,295 patients (94.7%), while 675 patients (5.2%) showed clinical improvement and only 16 patients (0.1%) reported no improvement. Clinical cure rates were comparable between pediatric and adult populations (93.8% vs. 94.8%, respectively).

Conclusions: Co-amoxiclav demonstrated high rates of clinical cure and overall treatment success in patients with URTIs across pediatric and adult populations, supporting its effectiveness in routine clinical practice when appropriately prescribed for suspected bacterial respiratory infections.

Keywords: Antimicrobial stewardship, Antibiotic prescribing patterns, Respiratory bacterial infections, Treatment outcomes

INTRODUCTION

Upper respiratory tract infections (URTIs) are among the most common infections encountered in outpatient

practice and represent a major reason for healthcare visits, antibiotic use, and work or school absenteeism worldwide. URTIs encompass a range of conditions, including acute pharyngitis, tonsillitis, AOM, sinusitis, and laryngitis,

affecting both children and adults. Although most URTIs are viral in origin and resolve spontaneously, bacterial infections and secondary bacterial complications continue to contribute to morbidity and may require appropriate antimicrobial therapy.^{1,2}

The management of bacterial URTIs focuses on achieving rapid symptom relief, preventing complications, limiting disease transmission, and improving patients' quality of life. Selecting an appropriate antibiotic is particularly important given the growing concern of antimicrobial resistance. Amoxicillin-clavulanate (co-amoxiclav) is a well-established combination of a β -lactam antibiotic and a β -lactamase inhibitor that offers broad-spectrum activity against common respiratory pathogens. These include β -lactamase-producing strains of *Haemophilus influenzae* and *Moraxella catarrhalis*, as well as susceptible strains of *Streptococcus pneumoniae* and *Streptococcus pyogenes*.^{3,4}

Current evidence-based guidelines recommend amoxicillin or amoxicillin-clavulanate as first-line treatment for selected bacterial URTIs, including acute bacterial rhinosinusitis, AOM, and certain cases of pharyngotonsillitis.⁵⁻⁷ Co-amoxiclav is particularly useful when β -lactamase-producing organisms are suspected, there is a history of previous antibiotic use, or broader antimicrobial coverage is considered clinically appropriate.^{3,5-6}

Although randomized controlled trials have established the efficacy and safety of co-amoxiclav in respiratory tract infections, patients enrolled in clinical trials may differ from those encountered in routine clinical practice. Therefore, RWE studies have become increasingly important, as they assess treatment effectiveness under everyday clinical conditions and capture diverse patient populations, variations in prescribing practices, and a wide range of clinical presentations.^{8,9}

Despite the widespread use of co-amoxiclav for the treatment of URTIs, large-scale RWE on prescribing patterns and clinical outcomes across both pediatric and adult populations remains limited. Such evidence is important for understanding treatment effectiveness in routine clinical practice and for supporting evidence-based antimicrobial stewardship initiatives.^{8,9}

Therefore, this multicenter, retrospective, medical record-based RWE study was conducted to evaluate the effectiveness and safety of co-amoxiclav in the treatment of URTIs. The study also aimed to describe the demographic and clinical characteristics of pediatric and adult patients, as well as co-amoxiclav prescribing patterns and dosing practices in routine clinical practice.

METHODS

Study design and population

This was a multicenter, retrospective, medical record-based RWE study conducted across participating

healthcare centers in India. The study evaluated the clinical effectiveness and prescribing patterns of co-amoxiclav in patients diagnosed with URTIs and managed in routine clinical practice. Patients who had received co-amoxiclav for the treatment of URTIs were included in the analysis. Both pediatric (≤ 12 years) and adult (> 12 years) patients were considered eligible for inclusion. Patients with incomplete or missing medical records that precluded assessment of demographic characteristics, treatment details, or clinical outcomes were excluded from the final analysis. A total of 12,986 eligible patients were included in the study.

Data collection

Data were retrospectively extracted from patient medical records using a predefined data collection format. Information collected included patient demographics (age and sex), clinical diagnosis, duration of illness prior to treatment initiation, co-amoxiclav formulation and dosage strength prescribed, frequency of administration, duration of therapy, and treatment outcomes. Clinical diagnoses included unspecified URTI, tonsillitis, AOM, pharyngitis, sinusitis, and laryngitis. Treatment outcomes were assessed by the treating physician and categorized as cure, improvement, or no improvement based on clinical response documented in the medical records.

Study endpoints

The primary endpoint was the assessment of clinical effectiveness of co-amoxiclav, measured by the proportion of patients achieving clinical cure, improvement, or overall clinical success (cure plus improvement). Secondary endpoints included evaluation of prescribing patterns, dosage forms utilized, dosing frequency, and age-wise distribution of clinical diagnoses among patients receiving co-amoxiclav.

Statistical analysis

Data was analyzed using descriptive statistics. Continuous variables were summarized as mean $\pm$ standard deviation (SD), while categorical variables were presented as frequencies and percentages. Analyses were performed for the overall population and stratified by pediatric (≤ 12 years) and adult (> 12 years) age groups.

Clinical effectiveness was assessed based on the proportions of patients achieving cure, improvement, and overall clinical success.

Ethical considerations

The study was conducted in accordance with the ethical principles of the Declaration of Helsinki, the International Council for Harmonization (ICH) Good Clinical Practice guidelines, and applicable local regulatory requirements. Institutional Ethics Committee (IEC) approval/waiver was obtained prior to the commencement of the study. As this

was a retrospective medical record-based study utilizing anonymized patient data, no direct patient intervention was involved, and patient confidentiality was strictly maintained throughout the study.

RESULTS

A total of 12,986 patients with URTIs who received co-amoxiclav at participating centers were included in this multicenter, retrospective RWE analysis. Patient demographics, clinical characteristics, prescribing patterns, and treatment outcomes were evaluated in pediatric (≤ 12 years) and adult (> 12 years) populations.

Patient demographics and baseline characteristics

A total of 12,986 patients diagnosed with URTIs and treated with co-amoxiclav were included in this multicenter, retrospective analysis. Of these, 1,116 patients (8.6%) were aged ≤ 12 years, while 11,870 patients (91.4%) were aged > 12 years.

Overall, the study population comprised 9,686 males (74.6%) and 3,300 females (25.4%). Among pediatric patients aged ≤ 12 years, 782 (70.1%) were male and 334 (29.9%) were female. Among patients aged > 12 years, 8,904 (75.0%) were male and 2,966 (25.0%) were female. Baseline demographic characteristics of the study population are presented in Table 1.

The mean age of patients aged ≤ 12 years was 8.12 ± 2.12 years (range: 3–12 years), while those aged > 12 years had a mean age of 36.09 ± 15.01 years (range: 13–88 years).

The mean duration of illness before initiation of treatment was 3.95 ± 1.81 days in the pediatric population and 4.25 ± 2.14 days in patients aged > 12 years. The mean duration of co-amoxiclav treatment was comparable between the two groups, at 5.61 ± 1.61 days in pediatric patients and 5.65 ± 1.62 days in patients aged > 12 years.

Clinical diagnosis

Unspecified URTI was the most common diagnosis, reported in 10,601 patients (81.6%), followed by tonsillitis in 993 patients (7.6%), AOM in 626 patients (4.8%), pharyngitis in 403 patients (3.1%), sinusitis in 287 patients (2.2%), and laryngitis in 76 patients (0.6%). The distribution of diagnoses is presented in Figure 1.

Among pediatric patients aged ≤ 12 years, unspecified URTI was the most commonly reported diagnosis, accounting for 973 patients (87.2%), followed by AOM in 108 patients (9.7%), tonsillitis in 19 patients (1.7%), sinusitis in 10 patients (0.9%), and pharyngitis in 6 patients (0.5%). No cases of laryngitis were reported among the pediatric patients. The distribution of diagnoses is presented in Figure 2.

Similarly, among patients aged > 12 years, unspecified URTI was the most common diagnosis, reported in 9,628 patients (81.1%), followed by tonsillitis in 974 patients (8.2%), AOM in 518 patients (4.4%), pharyngitis in 397 patients (3.3%), sinusitis in 277 patients (2.3%), and laryngitis in 76 patients (0.6%). The distribution of diagnoses is presented in Figure 2.

Prescribing pattern of co-amoxiclav

Among pediatric patients aged ≤ 12 years ($n=1,116$), co-amoxiclav suspension formulations were prescribed more frequently than tablet formulations, accounting for 721 patients (64.6%) and 395 patients (35.4%), respectively. The 457 mg/5 mL suspension was the most commonly prescribed formulation, used in 466 patients (41.8%), followed by 625 mg tablets in 375 patients (33.6%), 228.5 mg/5 mL suspension in 217 patients (19.4%), 642.9 mg/5 mL suspension in 38 patients (3.4%), and 375 mg tablets in 20 patients (1.8%). The distribution of co-amoxiclav formulations is presented in Figure 3.

Among patients aged > 12 years ($n=11,870$), co-amoxiclav tablet formulations were prescribed almost exclusively, accounting for 11,861 patients (99.9%), compared with 9 patients (0.1%) who received suspension formulations. The 625 mg tablet was the most commonly prescribed formulation, used in 11,802 patients (99.4%), followed by 1 g tablets in 39 patients (0.3%), 375 mg tablets in 20 patients (0.2%), 228.5 mg/5 mL suspension in 4 patients ($< 0.1\%$), 457 mg/5 mL suspension in 4 patients ($< 0.1\%$), and 642.9 mg/5 mL suspension in 1 patient ($< 0.1\%$). The distribution of co-amoxiclav formulations is presented in Figure 4.

Frequency of administration

Among pediatric patients aged ≤ 12 years ($n=1,116$), co-amoxiclav was predominantly prescribed as twice-daily (BID) therapy, with 951 patients (85.2%) receiving BID dosing and 165 patients (14.8%) receiving thrice-daily (TID) dosing. BID administration was the most frequently prescribed dosing schedule across all suspension strengths. Similarly, among patients receiving tablet formulations, most were prescribed BID therapy, while only a small proportion received TID dosing. The distribution of dosing frequency is presented in Figure 5.

Among patients aged > 12 years ($n=11,870$), co-amoxiclav was predominantly prescribed as twice-daily (BID) therapy, with 8,368 patients (70.5%) receiving BID dosing and 3,502 patients (29.5%) receiving thrice-daily (TID) dosing. The 625 mg tablet was the most frequently prescribed formulation in both dosing groups, administered to 8,304 patients in the BID group and 3,498 patients in the TID group. Other formulations were prescribed in only a small proportion of patients, regardless of dosing frequency. The distribution of dosing frequency and formulations is presented in Figure 6.

Clinical outcomes

Overall, clinical success was observed in 12,970 of 12,986 patients (99.88%) treated with co-amoxiclav. Complete clinical cure was achieved in 12,295 patients (94.7%), while 675 patients (5.2%) showed clinical improvement. Only 16 patients (0.1%) reported no improvement following treatment.

Among pediatric patients aged ≤ 12 years ($n=1,116$), complete clinical cure was achieved in 1,047 patients (93.8%), while 67 patients (6.0%) showed clinical improvement. Only 2 patients (0.2%) reported no improvement, resulting in an overall treatment success rate of 99.8% when cure and improvement were combined.

Among patients aged >12 years ($n=11,870$), complete clinical cure was achieved in 11,248 patients (94.8%), while 608 patients (5.1%) showed clinical improvement. Only 14 patients (0.1%) reported no improvement following treatment, resulting in an overall treatment success rate of 99.9% when cure and improvement were combined (Figure 7).

Overall, co-amoxiclav demonstrated consistently high clinical effectiveness in both pediatric and adult populations, with clinical success rates exceeding 99% across age groups. These favorable outcomes from a large and diverse real-world cohort support the use of co-amoxiclav as an effective treatment option for upper respiratory tract infections when appropriately prescribed.

Table 1: Demographic characteristics of the study population.

Characteristics	≤ 12 years ($n=1116$)	>12 years ($n=11870$)	Overall ($n=12986$)
Male	782 (70.1)	8904 (75.0)	9686 (74.6)
Female	334 (29.9)	2966 (25.0)	3300 (25.4)
Mean age $\pm$ SD (in years)	8.12 $\pm$ 2.12	36.09 $\pm$ 15.01	36.05 $\pm$ 15.03
Age range (in years)	3-12	13-88	3-88

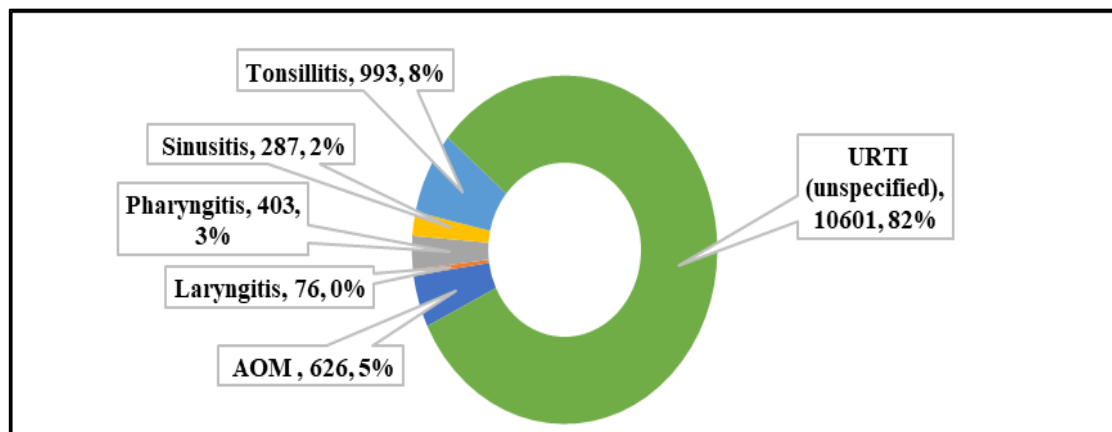


Figure 1: Distribution of clinical diagnoses among patients with URTIs.

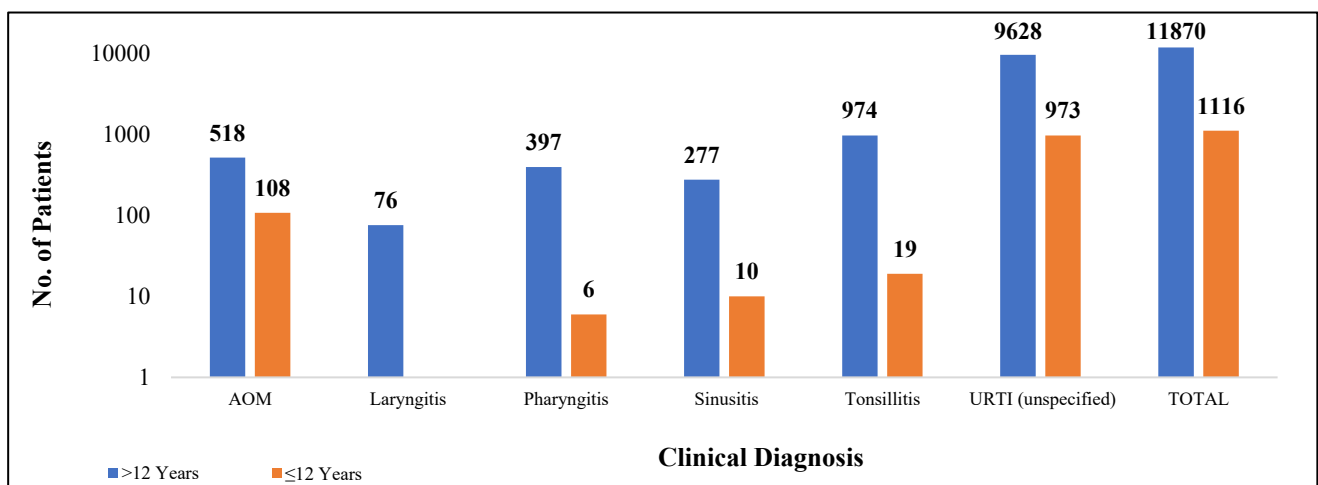


Figure 2: Age-stratified distribution of clinical diagnoses among patients with URTIs.

*Note (for figure 2): No cases of laryngitis were reported in patients aged ≤ 12 years ($n=0$).

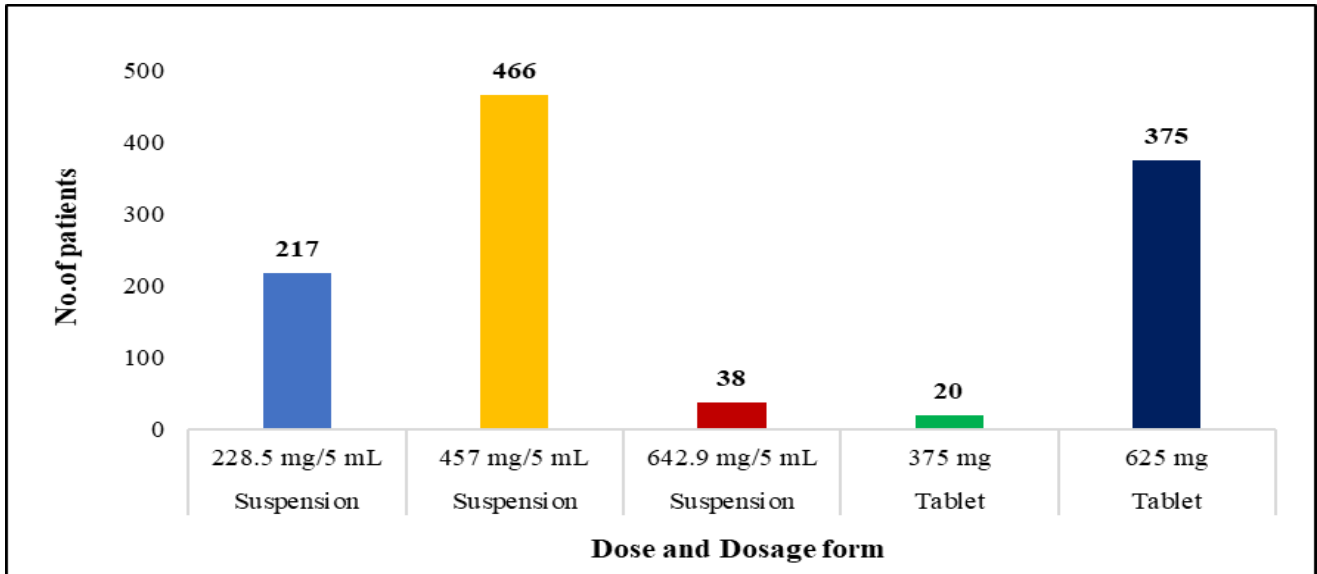


Figure 3: Distribution of co-amoxiclav formulations and dosage strengths among pediatric patients (≤12 years).

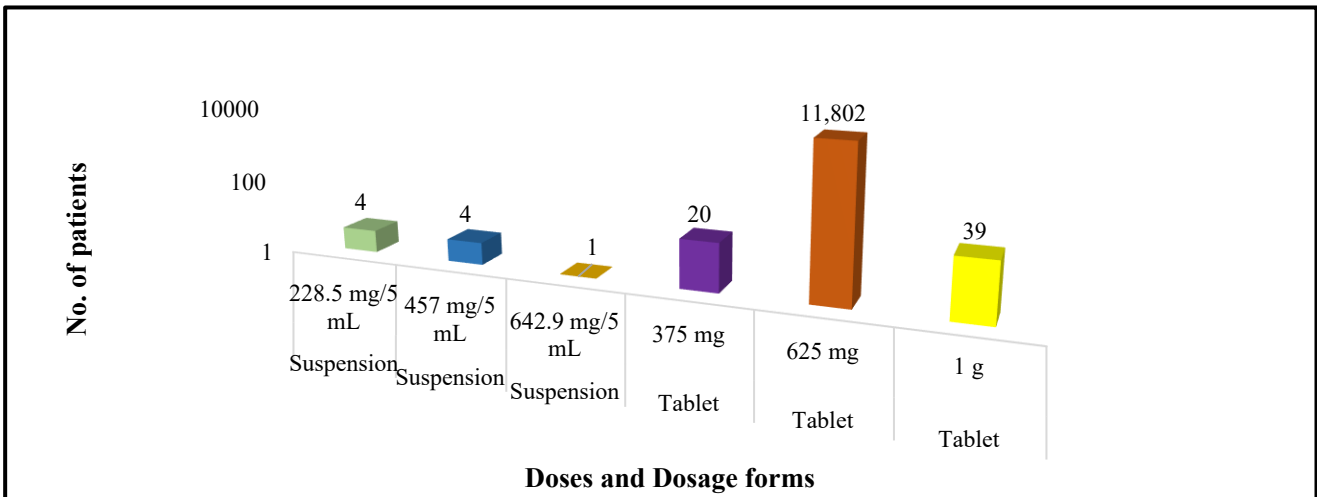


Figure 4: Distribution of co-amoxiclav formulations and dosage strengths among patients aged >12 years.

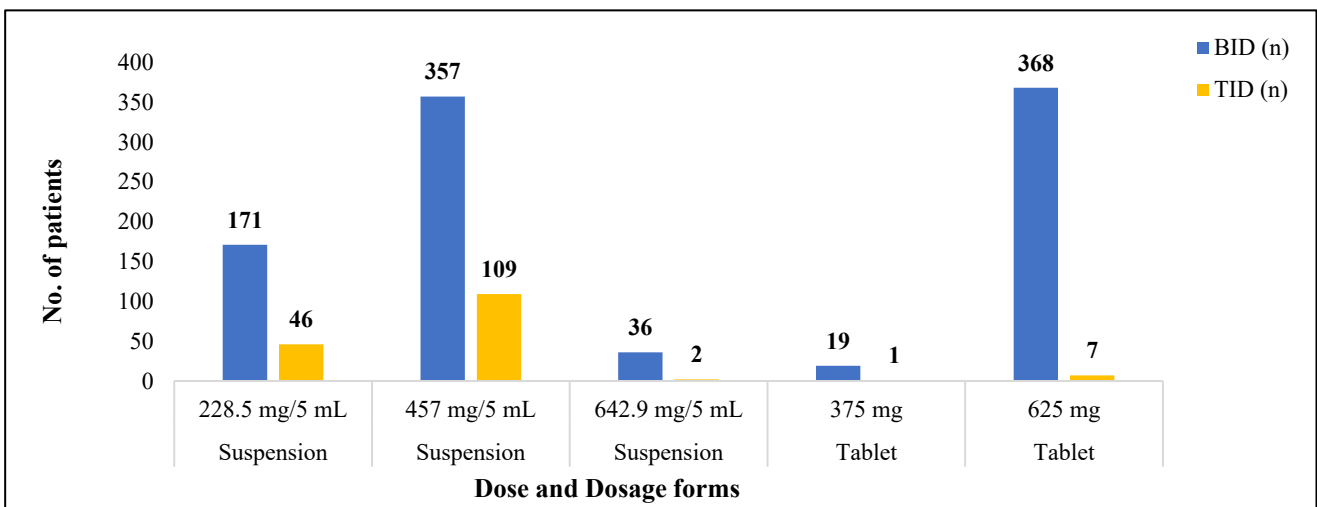


Figure 5: Distribution of BID and TID co-amoxiclav dosing regimens by dosage strength among patients aged ≤12 years (n=1,116).

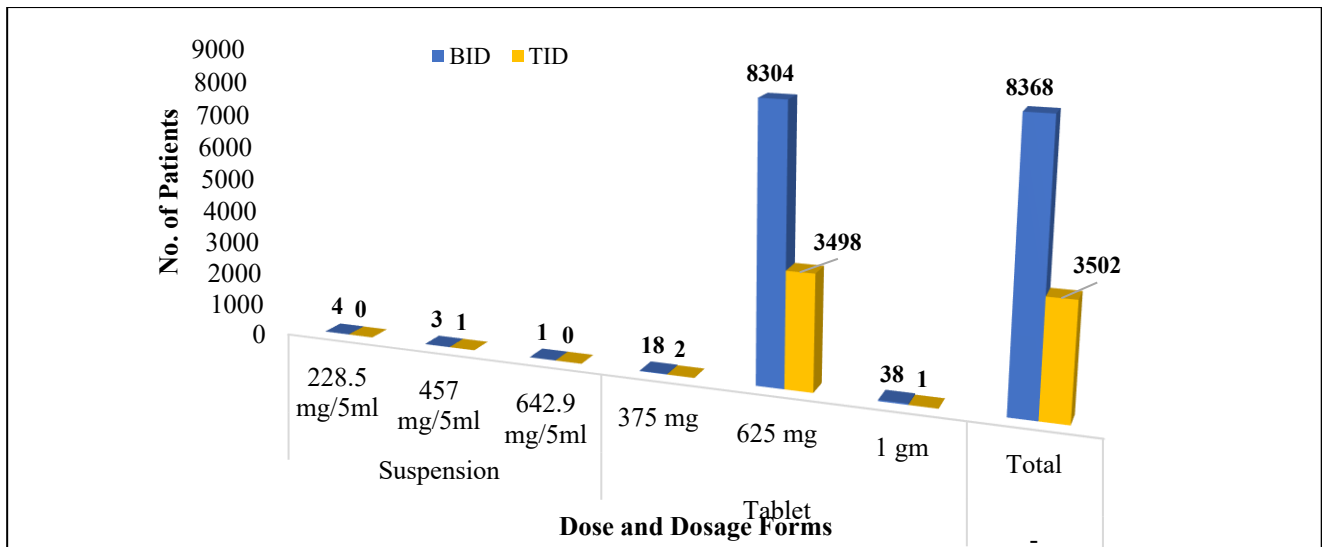


Figure 6: Distribution of BID and TID co-amoxiclav dosing regimens by dosage strength among patients aged >12 years (n=11,870).

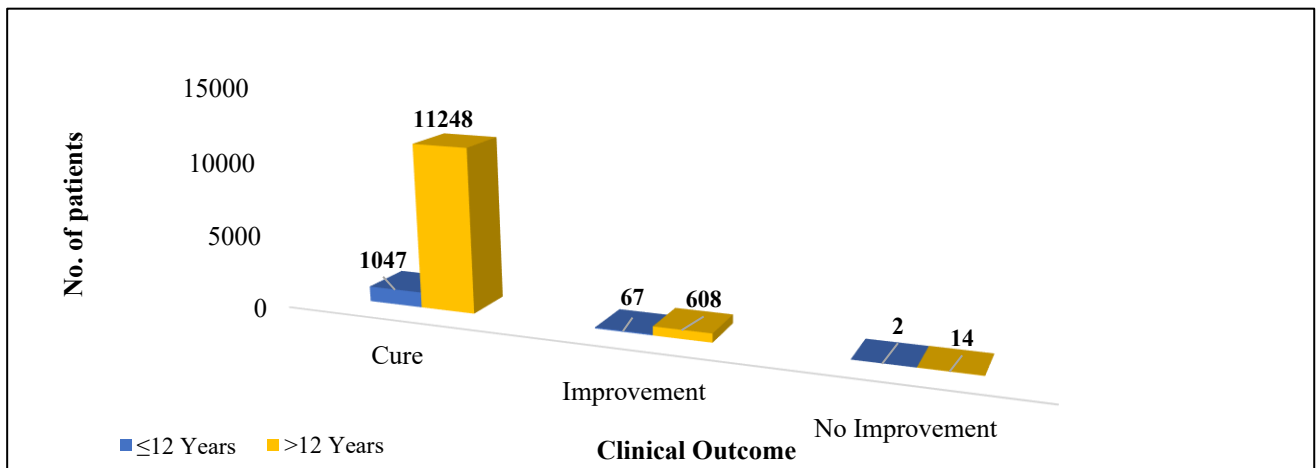


Figure 7: Distribution of clinical outcomes among pediatric (≤12 years) and adult (>12 years) patients treated with co-amoxiclav.

DISCUSSION

The present multicenter, retrospective RWE study evaluated the effectiveness of co-amoxiclav in 12,986 patients with URTIs treated in routine clinical practice. Complete clinical cure was achieved in 94.7% of patients, while the overall clinical success rate, defined as cure or improvement, was 99.88%, indicating favorable treatment outcomes in this large real-world population. However, given the observational study design and the absence of routine microbiological confirmation, these findings should be interpreted as evidence of treatment effectiveness among patients who were selected to receive antibiotic therapy in routine clinical practice, rather than as evidence supporting antibiotic use for all patients with URTIs.

URTIs are among the most common conditions encountered in ambulatory clinical practice. Most

uncomplicated URTIs are viral in origin, self-limiting, and generally do not require antibiotic treatment. Eccles and Cherry have highlighted the predominantly viral etiology of common respiratory illnesses in adults and children, respectively.^{1,2} Accordingly, antibiotic prescribing requires appropriate clinical judgment to identify patients with suspected bacterial infection or bacterial complications.

The predominance of unspecified URTI diagnoses in this study may reflect the diagnostic challenges encountered in routine clinical practice, where viral and bacterial respiratory infections can present with overlapping clinical features and microbiological testing is not routinely performed. Brook identified *S. pneumoniae*, *H. influenzae*, and *M. catarrhalis* as important bacterial respiratory pathogens and highlighted the growing concern of antimicrobial resistance.³ The continued clinical importance of *S. pneumoniae*, along with its evolving

antimicrobial susceptibility patterns, has also been highlighted by Feldman and Anderson.⁴

The high clinical success observed in this study is consistent with the established antibacterial spectrum of co-amoxiclav. Amoxicillin provides activity against susceptible respiratory pathogens, while the addition of clavulanic acid extends its coverage to many β -lactamase-producing organisms, particularly *H. influenzae* and *M. catarrhalis*.³ Nevertheless, antimicrobial stewardship remains essential, and broad-spectrum antibiotics should not be routinely prescribed for uncomplicated viral infections.

Our findings are broadly consistent with existing evidence supporting the use of amoxicillin-clavulanate in selected bacterial respiratory infections. The IDSA guideline recommends amoxicillin-clavulanate as empiric therapy for acute bacterial rhinosinusitis, particularly when infection with β -lactamase-producing pathogens is a concern.⁵ In contrast, penicillin or amoxicillin remains the preferred treatment for group A *Streptococcal* pharyngitis, while broader-spectrum agents such as co-amoxiclav are not routinely recommended.⁷ Therefore, the favorable outcomes observed in this study support the appropriate use of co-amoxiclav in bacterial respiratory infections rather than its routine use for undifferentiated URTIs.

Previous studies provide useful context for interpreting these findings. Wald et al reported significantly better outcomes with amoxicillin-clavulanate than with placebo in children with acute bacterial sinusitis, whereas Garbutt et al observed only modest differences between amoxicillin-clavulanate and placebo among patients with clinically diagnosed sinusitis.^{10,11} Similarly, Shaikh et al reported a lower symptom burden and faster symptom resolution with amoxicillin-clavulanate compared with placebo (median, 7 vs. 9 days) in children with acute sinusitis. The benefit was more pronounced among children in whom bacterial pathogens were identified.¹² These findings emphasize the importance of bacterial etiology when evaluating antibiotic effectiveness.

In adults, Bucher et al found no significant difference in time to clinical cure between amoxicillin-clavulanate and placebo among patients with clinically diagnosed acute rhinosinusitis.¹³ These findings highlight that outcomes observed in real-world clinical practice may reflect both the effects of treatment and the natural course of clinically diagnosed respiratory illnesses. Therefore, the high cure rate observed in the present study should be interpreted as the outcome achieved among patients selected to receive treatment, rather than as an effect attributable solely to co-amoxiclav.

Our findings are also broadly consistent with recent RWE from India. In a prospective, multicenter phase IV study, Ray et al reported an overall cure rate of 82.8% and a combined cure or improvement rate of 100% among children treated with high-dose amoxicillin-clavulanate.¹⁴

The pediatric cure rate of 93.8% observed in the present study is consistent with these favorable outcomes. However, differences in study design, patient populations, and outcome assessment methods may account for the variation in reported cure rates across studies.

An additional finding was the consistency of treatment outcomes across age groups. Clinical cure was achieved in 93.8% of pediatric patients and 94.8% of adults, while overall clinical success exceeded 99% in both groups. Prescribing patterns were also appropriate to the age groups, with suspension formulations predominantly used in pediatric patients and tablet formulations in adults. Twice-daily administration was the most commonly prescribed dosing regimen, consistent with evidence suggesting that less frequent dosing schedules may improve treatment adherence.^{15,16} However, adherence was not directly evaluated in this study.

The findings should also be interpreted within the broader context of antimicrobial stewardship. Both the Indian Council of Medical Research (ICMR) and Infectious Diseases Society of America (IDSA) guidelines emphasize the importance of rational antibiotic use and avoiding unnecessary antimicrobial exposure.⁵⁻⁷ Therefore, the favorable outcomes observed in this study should not be interpreted as supporting indiscriminate use of co-amoxiclav. Rather, they provide RWE of its effectiveness when appropriately prescribed for suspected or confirmed bacterial respiratory infections.

Key strengths of this study include its large sample size, multicenter design, and inclusion of both pediatric and adult populations. RWE complements findings from randomized controlled trials by providing insights into treatment effectiveness in routine clinical practice and across broader and more diverse patient populations.^{8,9} These findings further highlight the value of RWE in complementing randomized controlled trials by providing insights into treatment effectiveness across heterogeneous patient populations encountered in routine clinical practice.¹⁷ However, several limitations should be acknowledged. These include the retrospective study design, lack of routine microbiological confirmation, absence of a comparator group, and potential variability in outcome assessment. In addition, limited information was available on treatment adherence, disease severity, prior antibiotic exposure, pathogen distribution, and antimicrobial susceptibility.

Despite these limitations, the large multicenter dataset and consistent outcomes across age groups provide valuable RWE on the clinical effectiveness of co-amoxiclav in patients with URTIs. Overall, the findings are consistent with published evidence demonstrating favorable outcomes with amoxicillin-clavulanate in the appropriately selected bacterial respiratory infections, while also reinforcing the importance of judicious antibiotic prescribing and the responsible antimicrobial stewardship.

CONCLUSION

This large, multicenter, retrospective real-world study demonstrated high rates of clinical cure and overall clinical success among patients receiving co-amoxiclav for URTIs, with comparable outcomes observed in pediatric and adult populations. These findings are consistent with published clinical evidence supporting the effectiveness of amoxicillin-clavulanate in selected bacterial respiratory infections. However, given the predominantly viral nature of uncomplicated URTIs and the absence of a comparator group or routine microbiological confirmation in the present study, the findings should be interpreted as evidence of favorable treatment outcomes in routine clinical practice rather than as evidence of the necessity or superiority of co-amoxiclav for all URTIs. Appropriate patient selection and adherence to antimicrobial stewardship principles remain essential when considering co-amoxiclav therapy.

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Ethical approval: The study was approved by the Institutional Ethics Committee

REFERENCES

- Eccles R. Understanding the symptoms of the common cold and influenza. *Lancet Infect Dis.* 2005;5(11):718-25.
- Cherry JD. The common cold. In: Feigin and Cherry's Textbook of Pediatric Infectious Diseases. 8th ed. Philadelphia: Elsevier. 2019.
- Brook I. Microbiology and management of respiratory tract infections in children. *J Fam Pract.* 2003;52(12):S8-15.
- Feldman C, Anderson R. Recent advances in the epidemiology and prevention of Streptococcus pneumoniae infections. *F1000Res.* 2020;9:F1000.
- Chow AW, Benninger MS, Brook I, Brozek JL, Goldstein EJ, Hicks LA, et al. IDSA clinical practice guideline for acute bacterial rhinosinusitis in children and adults. *Clin Infect Dis.* 2012;54(8):e72-112.
- Indian Council of Medical Research. Guidelines. New Delhi: Indian Council of Medical Research. Available at: <https://www.icmr.gov.in/guidelines>. Accessed on 05 August 2026.
- Shulman ST, Bisno AL, Clegg HW, Gerber MA, Kaplan EL, Lee G, et al. Clinical practice guideline for the diagnosis and management of group A streptococcal pharyngitis: 2012 update by the IDSA. *Clin Infect Dis.* 2012;55(10):e86-e102.
- Sherman RE, Anderson SA, Dal Pan GJ, Gray GW, Gross T, Hunter NL, et al. Real-world evidence: what is it and what can it tell us? *N Engl J Med.* 2016;375(23):2293-7.
- Blonde L, Khunti K, Harris SB, Meizinger C, Skolnik NS. Interpretation and impact of real-world clinical data for the practicing clinician. *Adv Ther.* 2018;35(11):1763-74.
- Wald ER, Chiponis D, Ledesma-Medina J. Comparative effectiveness of amoxicillin and amoxicillin-clavulanate potassium in acute paranasal sinus infections in children: a double-blind, placebo-controlled trial. *Pediatrics.* 1986;77(6):795-800.
- Garbutt JM, Goldstein M, Gellman E, Shannon W, Littenberg B. A randomized, placebo-controlled trial of antimicrobial treatment for children with clinically diagnosed acute sinusitis. *Pediatrics.* 2001;107(4):619-25.
- Shaikh N, Hoberman A, Shope TR, Jeong JH, Kurs-Lasky M, Martin JM, et al. Identifying children likely to benefit from antibiotics for acute sinusitis: a randomized clinical trial. *JAMA.* 2023;330(4):349-58.
- Bucher HC, Tschudi P, Young J, Périat P, Züst H, et al. Effect of amoxicillin-clavulanate in clinically diagnosed acute rhinosinusitis: a placebo-controlled, double-blind, randomized trial in general practice. *Arch Intern Med.* 2003;163(15):1793-8.
- Ray R, Manavadaria AD, Mitra M, Gandhi S, Yadav N, Wari P, et al. Clinical outcomes with high-dose amoxycillin-clavulanate suspension in children with respiratory tract infections: a prospective, multicentre, phase IV study in India. *Adv Ther.* 2026;NA.
- Llor C, Bayona C, Hernández S, Moragas A, Miravittles M. Comparison of adherence between twice- and thrice-daily regimens of oral amoxicillin/clavulanic acid. *Respirology.* 2012;17(4):687-92.
- Falagas ME, Karageorgopoulos DE, Moraitis LI, Vouloumanou EK, Roussos N, Peppas G, et al. Compliance with once-daily versus twice or thrice-daily administration of antibiotic regimens: a meta-analysis of randomized controlled trials. *PLoS One.* 2015;10(1):e0116207.
- Lamdhade V, Warhade K, Gondane A, Pal A, Marda U, Pawar D, Sharma A. Multicenter, retrospective, real-world evidence study to evaluate the effectiveness of cefpodoxime in the management of patients with respiratory tract infections. *Int J Med Pharm Res.* 2026;7(2):3664-70.

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